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Guidance for the Reregistration of Pesticide Products Containing Ethephon as the Active Ingredient

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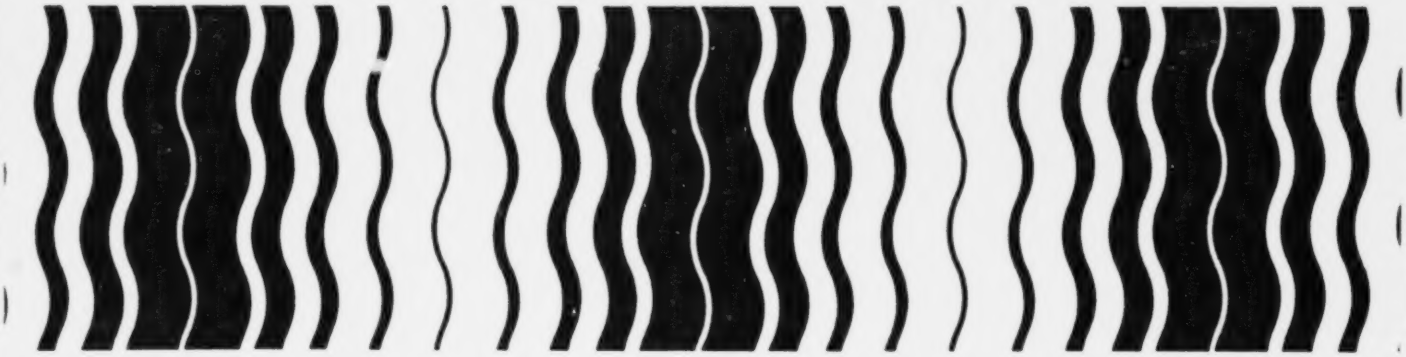
Guidance for the Reregistration of Pesticide Products Containing ETHEPHON as the Active Ingredient



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GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

ETHEPHON

AS THE ACTIVE INGREDIENT

CASE NUMBER 0382

CAS NUMBER 16672-87-0

Chemical Code 099801

September 1988

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

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GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. Also known as the Reference Dose or RfD.
a.i.	active ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
EEC	Estimated Environmental Concentration. The estimated pesticide concentration system in an environment, such as a terrestrial ecosystem.
EP	End Use Product
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FR	Federal Register
HDT	Highest Dose Tested
LC50	Median lethal concentration - a statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water or feed, e.g., mg/l or ppm.
LD50	Median lethal dose - a statistically derived single dose than can be expected to cause death in 50% of the test animals, when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LDT	Lowest Dose Tested
LEL	Lowest Effect Level
MP	Manufacturing Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted to the Agency.

MTD	Maximum Tolerated Dose
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs
OES	Office of Endangered Species, U.S. Fish and Wildlife Service
PADI	Provisional Acceptable Daily Intake
ppm	parts per million
RBC	Red Blood Cell (s)
RfD	Reference Dose
TAS	Tolerance Assessment System
TMRC	Theoretical Maximal Residue Contribution

I. INTRODUCTION

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

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[1] The scientific reviews and Compendium of Uses may be obtained from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161. Tel: (703) 487-4650.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submittal of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants must notify the Agency of any information, including interim or preliminary results of studies, if that information suggests possible adverse effects on man or the environment. This requirement is independent of the specific time requirements imposed by EPA for submittal of completed studies called in by the Agency and continues as long as the products are registered under FIFRA.

II. CHEMICAL COVERED BY THIS STANDARD

A. Description of Chemical

Common Name (ANSI) : Ethephon

Chemical Name : (2-Chloroethyl) Phosphonic acid

Empirical Formula : $C_2H_6CLO_3P$

Molecular Weight : 144.5

Physical State : Waxy, solid

Color : White

Melting Point : 74 to 75C

Solubility : Very soluble in water, alcohol, propylene glycol; slightly soluble in aromatic solvents

Trade Name : Bromeflor, Cerone, Chlorethephon (N. Zealand), Ethrel, Florel, Prep, and Flordimex

OPP/Shaugnessy No.: 099801

CAS Registry No. : 16672-87-0

Wiswesser Line-Formula Notation: QPQO2G

Date of Initial Registration: 1973

Ethephon was discovered in 1965 and introduced commercially in 1973 by the AmChem/Union Carbide Company for inducing flowers on pineapples in Hawaii. At the present time, Rhone-Poulenc is the only registrant of ethephon, having purchased Union Carbide's registrations.

The following data have been required under Section 3(c)(2)(B) of FIFRA:

STUDY	DUE DATE
Oncogenicity Study species other than rat	March 1989
Teratogenicity Study species other than rat	May 1987 (submitted)

The regulatory conclusions regarding the teratogenicity study are discussed in part III (Agency Assessment).

B. Use Profile

Ethephon, a plant growth regulator that generates ethylene gas, is used on many crops to promote fruit ripening, abscission, flower induction, breaking of apical dominance, and many other plant responses. Ethephon is applied broadcast to plant foliage by ground or aerial equipment when the plant is reaching maturity, usually the pre-flower stage. Ethephon releases the natural plant hormone ethylene after application and the ethylene produces the growth effects in the plants.

Cotton, tomatoes, grapes, and tobacco account for 98% of the current use of ethephon in agriculture (approximately 1,135,000 acres). Other sites include apples, barley, wheat, blackberries, boysenberry, blueberry, cantaloupe, cherry (tart and sweet), cucumber, squash and pumpkin (hybrid seed production), figs, cucumber (pickling), filberts, lemon, tangerine, tangelo, pepper, pimento, walnut, ornamentals, guava, grapes for table and raisin production, pineapples, sugarcane, coffee beans, cottonseed, macadamia nuts, trees (forest and shelterbelt) and cranberries.

Application rates vary from 0.08 to 2.0 pounds of active ingredient per acre depending upon the use site and desired effects.

There are two emulsifiable concentrates, seven soluble concentrates/liquids, and two ready-to-use liquids available for crop use. There is one 98% active ingredient technical product.

Rhone-Poulenc is currently the sole manufacturer of the technical product and formulator of the end-use products in the U.S.A.

III. AGENCY ASSESSMENT

The Agency has conducted a thorough review of the scientific data base available for ethephon. This part of the standard sets forth the results of that review.

A. Toxicological Assessment

1. Acute Oral, Dermal and Inhalation Toxicity

Acute toxicity studies show that via the oral and dermal routes, ethephon is relatively non-toxic except in hens (see oral neurotoxicity study). An acute study with rats showed an oral LD_{50} of 1.6 g/kg (Toxicity Category III). An acute dermal study using rabbits showed a dermal LD_{50} of > 5 g/kg (Toxicity Category III). No adequate data are available on the acute inhalation properties of ethephon. Acute inhalation data is required (refer to Table A of this document).

2. Irritation and Sensitization (dermal and eye)

Sufficient data are available to show that the technical grade of ethephon is extremely irritating to the skin. Based upon an acceptable primary dermal irritation study in rabbits, ethephon has been placed in Toxicity Category I for this effect.

There are no acceptable data on the primary eye irritation effects of ethephon. However, ethephon is presumed to be extremely irritating (corrosive) to the eyes (Toxicity Category I irritant), based on the primary skin irritation study described above which indicates that ethephon is corrosive. An eye irritation study is not reqired.

No data are available on the dermal sensitization properties of ethephon.

3. Acute Delayed Oral Neurotoxicity

Ethephon was found to be acutely toxic in the hen with an LD_{50} of 3.8 g/kg. No dose related neuro-histopathology was detected in the hens after 42 days at acute dose levels.

4. Subchronic Toxicity

No adequate data are available on subchronic oral toxicity in rats or dogs. However, the requirement for subchronic studies in the rodent and non-rodent will be waived if the required chronic studies are acceptable. There are two supplementary studies, one for the rat and one for dogs, neither of which demonstrated a NOEL.

Rat:

In the rat study, ethephon was administered by gavage for 13 weeks to 20 rats per sex per dose level at 0, 50, 100, and 200 mg/kg/day. Plasma cholinesterase and brain cholinesterase activity were found to be statistically significantly different from the controls at all dose levels. Red blood cell cholinesterase activity did not differ from the controls in any dose group of males or females.

Dog:

In the dog study, ethephon was administered in the food to 4 dogs per sex per dose level at 0, 5.0, 25.0 and 187.5 mg/kg/day for 13 weeks. Plasma cholinesterase activity was statistically significantly depressed in both males and females at all dosage levels. Red blood cell cholinesterase activity was statistically significantly depressed in the males (at all dose levels except 5.0 mg/kg/day at 8 weeks) and at the 25.0 and 187.5 mg/kg/day dose levels in the females. Brain cholinesterase activity was statistically significant only in females dosed at 187.5 mg/kg/day.

A subchronic dermal test is also required (21-days) because no data are available. A special smoke inhalation study (21-day) is required because the existing study is supplementary and ethephon is registered for use on tobacco.

5. Chronic Toxicity and Oncogenicity

Chronic Toxicity

The available chronic toxicity data for ethephon are not adequate. Studies are required for the rodent and non-rodent.

Rat:

An available rat study is supplementary because data were not submitted on the stability of ethephon in the feed, and historical control data were not submitted on the incidence of pancreatic islet cell adenomas and carcinomas. Dose related non-oncogenic effects were limited to plasma and red blood cell cholinesterase inhibition in the highest dose tested (HDT). This inhibition was statistically significant in males and females for red blood cells only. The NOEL for cholinesterase activity effects in this study is 15 mg/kg/day. This study may be upgraded if the data on the stability of ethephon in the feed and the historical control data are submitted and found to be acceptable.

Dog:

An available dog study is supplementary because no NOEL was demonstrated and data were not submitted on the stability of ethephon in the feed. Red blood cell cholinesterase activity was depressed only at the two highest dose levels 50 and 75 mg/kg/day. 75 mg/kg/day was given to the dogs only from weeks 0 to 3 then the dosage was reduced to 50 mg/kg/day to these animals for weeks 4 and 5, and further reduced to 25 mg/kg/day for the remainder of the study. In the study there were two, apparently different, sources of the chemical tested and reported as source A and source B.

For Source A ethephon, reduced body weights were observed with a NOEL of 7.5 mg/kg/day. A NOEL for this effect was not demonstrated for source B ethephon. This study may be upgraded if the data on the stability of ethephon in the feed is submitted and found to be acceptable.

Mouse:

In a supplementary chronic toxicity/oncogenicity study, Swiss Albino mice, 85 per sex per group were fed diets containing 0, 4.5, 45, and 150 mg/kg/day of ethephon for 78 weeks. No stability data on ethephon in the feed were submitted, if collected. The oncogenic effects observed in this study are reported in the oncogenicity data discussion. The following chronic effects were observed in this study:

Inhibition of plasma cholinesterase activity was significant at the 45 and 150 mg/kg/day dose levels in males and females. The NOEL for plasma cholinesterase activity is 4.5 mg/kg/day for both sexes and the LEL for this effect was 45 mg/kg/day for both sexes.

There appeared to be a dose related decrease in red blood cell (RBC) cholinesterase activity in females. There was significant depression in RBC cholinesterase activity at the 45 and 150 mg/kg/day dose levels. Females in the 4.5 mg/kg/day dose group exhibited depression in RBC cholinesterase activity at 52 weeks (83% of control values) and 78 weeks (70% of control values), which was not statistically significant. Because of the apparent dose related decrease in RBC cholinesterase activity in females in the 4.5 mg/kg/day dose group, the NOEL for this effect in females is considered to be below 4.5 mg/kg/day, the lowest dose tested.

RBC cholinesterase activity was nominally decreased in males at the mid and high dose groups. These effects were not statistically significant.

Brain cholinesterase activity was no different from control values at any dose level in males or females.

Oncogenicity Data

The available data are not adequate to assess the oncogenic potential of ethephon.

Rat:

Oncogenic effects were equivocal in this part of the combined chronic/onco study. Feed containing ethephon at levels of 0, 1.5, 15, and 150 mg/kg/day was administered to 55

Sprague Dawley rats per sex per group. Slight increases which were not statistically significant, occurred in pancreatic islet cell adenomas and carcinomas in the 150 mg/kg/day dose group. No statistically significant oncogenic effect was demonstrated during the study or at termination. Depression of plasma and red blood cell cholinesterase activity were the only observed effects. Adequate historical control data must be submitted on pancreatic islet cell adenomas and carcinomas.

The study is supplementary because data were not submitted on the stability of ethephon in the feed, and historical control data were not submitted on the incidence of pancreatic islet cell adenomas and carcinomas. This study may be upgraded if these data are submitted and found to be acceptable. The highest dose tested (HDT) of 150mg/kg/day is considered to be the maximum tolerated dose (MTD) based on decreased red blood cell and plasma cholinesterase activity in males and females.

Mouse:

In a supplementary oncogenicity study, Swiss Albino mice, 85 per sex per group were fed diets containing 0, 4.5, 45, and 150 mg/kg/day of ethephon for 78 weeks. No stability data on ethephon in the feed were submitted. There was a statistically significant increased trend in fibrosarcomas in the females, but none of the values were statistically significantly different from controls. The incidence of hemopoietic carcinogenicity (leukemia, lymphocytic leukemia, thymic and nonthymic lymphoma, and reticulum cell sarcoma) was statistically significantly elevated only for females in the mid dose group. Historical control data were not submitted with this study and are needed to evaluate the potential oncogenicity of this compound. No consistent dose related changes occurred in body weight, food consumption, hematology, or organ weights.

Using inhibition of plasma and RBC cholinesterase as the criteria for determining whether an MTD was reached in this study, the MTD was reached for females because statisically significant inhibition of plasma and RBC cholinesterase was observed. In males, however, the finding of statisically significant inhibition of plasma cholinesterase and 21% inhibition of RBC cholinesterase indicated that probably 1/2 MTD was reached.

The study is supplementary because data were not submitted on the stability of ethephon in the feed and historical control data on fibrosarcomas were not submitted. This study may be upgraded if acceptable data are submitted.

6. Teratology and Reproductive Effects

Teratogenic and Fetotoxic Effects

Sufficient data are available on the teratogenic potential of ethephon in the rat and the rabbit to meet these data requirements.

Rat:

Ethephon was administered to rats by gavage at doses of 0, 200, 600, and 1800 mg/kg/day from day 6 through day 19 of gestation. Maternal toxicity occurred in the form of maternal death at the 1800 mg/kg/day dose level.

Fetal resorption was observed at the 1800 mg/kg/day dose level. However, this apparent effect (resorption) is equivocal, because of the small number of litters remaining for examination (9 of a possible 25 litters). The NOEL for maternal and embryo/fetal toxicity is 600 mg/kg/day. The NOEL for teratogenic effects is 600 mg/kg/day based on the dose related effects that were observed at the HDT. Because of maternal mortality at the HDT, there were not enough litters remaining to be statistically significant, however three of the remaining fetuses were deformed. Therefore the NOEL has been established at the level tested where no effects were demonstrated.

Rabbit:

Ethephon was administered to rabbits at doses of 0, 50, 100, 250 mg/kg/day by gavage from day 6 through 19 of gestation. Fetal resorptions were increased only in the 100 and 250 mg/kg/day dose groups, but they were statistically significant only at the 250 mg/kg/day dose level. Doses of 250 mg/kg/day resulted in depression of maternal cholinesterase levels, atoxia and an increased incidence of various clinical findings, and gross pathology in the gut. No effects were demonstrated in the 50 mg/kg/day dose group, which is designated as the NOEL.

Reproductive Effects:

Available data on the reproductive effects testing of the technical grade of ethephon are not acceptable. Another study is required.

The available study is classified as core supplementary because of the following deficiencies: 1) Data on individual animals were not reported. 2) Data from necropsies and histological examination were not reported. 3) Animal weights and food consumption were not reported with sufficient frequency to determine what if any effects occurred. 4) Clinical observations were not reported. 5) No measures of data variability were reported. 6) Biased methods may have been used in selecting pups for further study. 7) The method used in breeding and calculating indexes were ambiguous. 8) The test substance appears to be a formulated product of unspecified composition. 9) Diets were prepared weekly, but no data were submitted on the stability of ethephon in the feed.

7. Mutagenicity Data

a. Gene Mutation -

Sufficient data are available on the gene mutation potential of the technical grade of ethephon to demonstrate that the test substance is not mutagenic in the Ames Test.

Five strains of Salmonella typhimurium were tested up to the toxic concentration/limit dose of 100 ug/100 uL(10,000 ug/mL) with and without activation. No evidence of mutagenicity occurred.

b. Structural Chromosomal Aberrations -

Insufficient data are available from structural chromosomal aberration tests, because the identity of the test material was insufficiently characterized. Unless the identity, purity, and composition of the test material is submitted, another test is required.

Ethephon of unspecified purity was tested in the micronucleus test (indirect test for chromosomal aberrations) at toxic dose levels (200 mg/kg) in the mouse system. No evidence of mutagenicity occurred. In order for the study to be acceptable, the test material must be adequately identified.

c. Other Genotoxic Effects -

No acceptable data are available on other genotoxic effects. A gene mutation study in mammalian cells is required.

8. Metabolism

There are no available metabolism data. A rat metabolism study is required.

9. Information on Human Effects

Two studies were conducted on ethephon in humans. The Agency does not condone nor require human testing. These studies were available however, and the Agency considered all available data in its assessment of the effects of this pesticide.

In the first study, humans demonstrated some symptoms characteristic of anticholinesterase activity in a study of five humans per sex dosed with ethephon at an average dose level of 1.8 mg/kg/day. Subjects receiving the test compound reported the following symptoms and/or signs; the sudden onset of diarrhea or an urgency of bowel movements, stomach cramps or gas, an increased urgency and frequency of urination, and either a decrease or an increase in appetite. None of the control subjects had complaints similar to the test group. Plasma CHE and RBC CHE activities were similar to or higher than initial values in test subjects.

In the second human study, 10 humans per sex were dosed with ethephon at 0.5 mg/kg/day for 16 days, followed by a recovery period of 2 weeks. Dose related effects occurred in plasma cholinesterase activity, but not in red blood cell cholinesterase activity. The effect was reversible within 15 days. When the control group and test groups were compared, the decreased plasma cholinesterase activity was statistically significant. No dose related effects were seen in hematology, blood chemistry, or urine analyses.

It is not clear whether or not any of the symptoms in the first human study described, such as diarrhea, urgency of bowel movements, urinary urgency, or any other effects occurred in the humans during the dosing period of the second study, since symptoms and signs were not reported. Based on this study the NOEL for plasma cholinesterase inhibition in humans is <.5 mg/kg/day.

B. Human Exposure Hazard

1. Pesticide Incident Monitoring System (PIMS):

Ethephon usage has resulted in four cases of skin injury (irritation) reported from 1980 through 1986 in California, due to exposure to field residue. There were no physician-treated poisonings from 1980 through 1986 in California. There were no deaths reported in the U.S. (1961, 1969, 1973, 1974) and no deaths reported in California from 1965 to 1977 or from 1982 to 1986.

2. Protective Clothing

Technical grade ethephon is corrosive to the skin. A few cases of skin injury to field workers in California have been reported (see above PIMS information). Since ethephon has been found to be corrosive to the eyes and skin, protective clothing for mixers, loaders and applicators is required. Mixers, loaders and applicators must wear a full face shield, long trousers, long sleeved shirt, gloves, and boots to avoid as much skin and eye contact as possible.

3. Reentry

Reentry data are required by § 158.390 if the pesticide and its use patterns meet certain toxicity and exposure criteria. Ethephon meets the toxicity criteria of 40 CFR § 158.390 because it is classified as being extremely irritating to the skin (toxicity category I) and the Agency has received epidemiological evidence that residues of this pesticide can cause dermal irritation to persons entering treated sites. Ethephon also meets the exposure criteria of 40 CFR § 158.390 in that it is registered for use on grapes and other crops which have human tasks that could involve substantial exposure to the pesticide treated surfaces. Foliar and soil dislogeable residue data are required to estimate human exposure resulting from contact with treated foliage or soil.

Human exposure monitoring data may be submitted, but the data submitted should be limited to (1) foliar dislogeable residues where exposure to treated leaves would be likely and (2) edaphic dislogeable residues where there could be exposure to treated soils.

These data will be used to establish reentry intervals. Until these data are available, the the Agency is imposing interim reentry intervals of 24 hours for ethephon treated crops.

4. Possible Presence of Impurities

Available data indicate that technical ethephon products may contain 2-chloroethanol as an impurity. 2-Chloroethanol is extremely toxic via the inhalation route and has caused human deaths. Because of its volatility, 2-choroethanol is unlikely to be present in ethephon end use products in amounts high enough to pose an inhalation hazard. However, the impurity could pose a hazard when technical or manufacuring use products are stored or used in poorly ventilated spaces. Under these conditions, 2-chloroethanol vapors could accumulate to levels which may be hazardous to workers in the area. The Agency is requiring submission of product chemistry data to assess the extent of hazard posed by 2-choroethanol.

The Agency has also determined that another impurity, the mono-chloroethyl ester of (2-chloroethyl)-phosphonic acid, may be present in technical ethephon products. This substance degrades to form 2-choroacetic acid which is a metabolic inhibitor. Because of the toxicological significance of 2-chloroacetic acid, the Agency is requiring the submission of residue chemistry data to determine whether ethephon-treated commodities contain 2-chloroacetic acid residues.

C. Tolerance Reassessment

1. Tolerances Issued

Tolerances have been established for the residues of ethephon on various crops under 40 CFR 180.300, 40 CFR 185.2700 and and 40 CFR 186.2700. The following is a list of the established tolerances for ethephon. There are no CODEX maximum residue levels (MRL) for ethephon.

Commodity	Tolerance (ppm)
Grapes	2.0
Hogs, fat	0.1
Hogs, mbyp	0.1
Hogs, meat	0.1
Horses, fat	0.1
Horses, mbyp	0.1
Horses, meat	0.1
Lemons	2
Macadamia nuts	0.5
Milk	0.1
Peppers	30
Pineapples	2
Pineapple fodder	3
Pineapple forage	3
Pumpkins	0.1
Sheep, fat	0.1
Sheep, mbyp	0.1
Sheep, meat	0.1
Tangerines	0.5
Tangerine hybrids	0.5
Tomatoes	2
Walnuts	0.5

Commodity	Tolerance (ppm)
Wheat, grain	2.0
Wheat, straw	10.0
Guavas	0.1
Sugarcane Hawaii only	0.1

40 CFR 185.2700 and 185.2700 (food and feed additive)

Barley milling fractions except flour	5.0
Wheat milling fractions except flour	5.0
Raisins	12.0
Raisin waste	65.0
Sugarcane molasses	1.5
Barley milling fractions except flour	5.0
Wheat milling fractions except flour	5.0

2. Residue Data

a. Metabolism

The nature of residues in plants is adequately understood. Ethephon degrades to ethylene, phosphate, and chloride. The parent compound, ethephon and the ethylene gas it produces are the major metabolites in plants. Plant metabolism data are not required. Acceptable metabolism data are also available for ruminants. The residue of concern in plant commodities, ruminant tissues and milk is ethephon per se. Additional data are required regarding metabolism in poultry tissues and eggs.

Upon receipt of the requested data on poultry metabolism, storage stability data, and data regarding the magnitude of the crop residues, the adequacy of the established tolerances for residues of ethephon in animal feed commodities will be assessed.

b. Possible Presence of Contaminant of Toxicological Concern

The Agency finds that residues of monochloroacetic acid may be found in ethephon-treated commodities. Monochloroacetic acid is a potential degradation product of an impurity in ethephon, monochloroethyl ester of (2-chloroethyl)-phosphonic acid. Monochloroacetic acid is an extremely toxic metabolic inhibitor and has been prohibited from addition to food under 21 CFR 189.155. Analysis of certain food and feed crops for residues of this contaminant are required as specified in Appendix I. A. If residues of monochloroacetic acid are detected, data may be required for all ethephon-treated commodities.

c. Analytical Methodology

Adequate gas-liquid chromatographic (GLC) methods are available for collection of data pertaining to residues of ethephon in or on plant and animal commodities. The Amchem-plant method is the recommended method for enforcement purposes for plant commodities other than wheat and barley straw. This method has been subjected to a successful method trial for pineapples and appears as Method I in PAM, Vol. II. The Amchem -cereal method is recommended for enforcement purposes for wheat and barley straw. This method has undergone a successful method trial for wheat and barley and has been forwarded to FDA for inclusion in the PAM, Vol. II as Method II. The Amchem -tobacco method, the Amchem-sugarcane method, the AMchem-cotton method, and the Amchem-citrus oil method are adequate for data collection.

The nature of the residue in poultry has not been adequately described. Therefore, the adequacy of available analytical methods for poultry products cannot be ascertained.

The Union Carbide-animal GLC method employing a flame-photometric detector, is the recommended method for enforcement purposes for milk and animal tissue. This method has undergone a successful method trial on milk and liver and has been forwarded to FDA for inclusion in the PAM, Vol. II as Method III. The Amchem-tissue GLC method using a phosphorous-specific alkali thermionic detector (ATD) is adequate for collection of data pertaining to residues in cattle and poultry tissues. The Union Carbide method is adequate for collection of data pertaining to residues in milk, meat and meat by-products but not in fat and liver. The Amchem-milk and tissue GLC/ATD method is inadequate for collection of data pertaining to animal tissues and milk because recovery is unacceptably low.

Ethephon has not been analyzed by multiresidue methods published in PAM Vol. I, Appendix II-Multiresidue Method Testing as required in 40 CFR 158.125(b)(15). In addition, representative plant samples, ruminant tissues and milk bearing residues of ethephon must be subjected to analysis by PAM Vol. I methods 211.1, 212.1, 231.1, 232.1 and 252. Protocols for multiresidue mehtods are available from the National Technical Information Service under Order No. PB 203734/AS.

The usefulness of existing residue data for poultry will be reassessed when the required poultry metabolism data have been evaluated. Also methods to be used for future data collection and enforcement will be determined after evaluation of the required analytical method validation data.

d. Residue Storage Stability

Residue storage stability data are available for sugarcane but not for other plant and animal commodities.

e. Field Residue Data

The available data support the established tolerances for residues of ethephon in or on pumpkins, sugarcane and sugarcane molasses, provided satisfactory storage stability are submitted. In addition, a PHI of $\geq$ 2 months must be implemented for sugarcane.

Additional residue data are required to support the established tolerances for residues in or on blackberries, coffee beans, cottonseed, cranberries, grapes, guavas, lemons, melons, pineapples, pineapple forage, tangerines, tomatoes, wheat grain and wheat straw.

The residue data requested on wheat grain, wheat straw, and the processed fractions of wheat will be used to assess the established tolerances for residues in or on barley grain, barley straw, and the processed fractions of barley. These wheat data can be used to support the tolerances for barley because of the similarity of the crops.

A tolerance must be proposed for residues of ethephon in or on the agricultural commodity sugarcane forage. Alternatively, a grazing restriction may be proposed.

f. Processing Data

Processing studies are needed on apples, citrus fruits, coffee beans, figs, pineapples, sugarcane, tomatoes and wheat grain.

Food/feed additive tolerances and supporting data are needed for residues in cottonseed meal, cottonseed refined oil, cottonseed soapstock, grape juice, dried grape pomace and raisins.

Pyrolysis products derived from ethephon must be characterized and the level if residue in tobacco smoke must be quantified.

g. Pre-harvest Intervals

Pre-harvest intervals (PHI) that are based upon actual field residue data reflecting the maximum proposed use rates are needed for applications of ethepon to apples, barley, blackberries, blueberries, cherries, coffee beans, cotton, cranberries, cucumbers, figs, filberts, grapes, guavas, melons, peppers, pineapples, tangerines, tomatoes, walnuts and wheat. In the interim, the PHI's listed in section D of this document must be placed on end-use product labeling for each crop.

h. Other findings

An English translation of product labels showing the use directions for the use of ethephon on coffee beans for importation to the U.S. are required.

The entry "pineapple fodder" must be deleted from 40 CFR 180.300 because pineapple fodder is considered a processed feed not a raw agricultural commodity.

The tolerance for residues in or on guava published in FR 45 (136):47147, must be added to the entries under 40 CFR 180.300 in order to provide a complete listing of residue tolerances under the appropriate CFR heading. Similarly, a food additive regulation for ethephon residues in raisins must be added to 21 CFR 193.186 in order to provide a complete listing of food additive tolerances under the appropriate CFR heading. CFR 180.300 currently designates "N" (negligible) for certain crop tolerance entries. The concept of negligible residues is no longer accepted by the Agency.

3. Dietary Assessment

The toxicology data considered to establish a provisional acceptable daily intake (PADI) include the following:

a. A 16-day study in humans where a decrease in plasma cholinesterase activity was observed at 0.5 mg/kg/day.

b. A 2-year feeding study in dogs (supplementary) that demonstrated a NOEL for reduced body weight of 7.5 mg/kg/day.

c. A 2-year feeding study in rats (supplementary) that demonstrated an NOEL for cholinesterase activity at 300 mg/kg/day.

d. Two teratogenicity studies, one in rats and one in rabbits. The rat NOEL was established at 600 mg/kg/day and the rabbit NOEL at 50 mg/kg/day.

The PADI for ethephon has recently been revised by the Agency ADI Committee and is now established at 0.005 mg/kg/day (0.5 mg/kg/day for a LEL, and an uncertainty factor of 100). This value is based on an LEL of 0.5 mg/kg/day for a decrease in plasma cholinesterase activity in a 16-day study in humans. An uncertainty factor of 100 is derived from a factor of 10 for the variation in the susceptibility of humans, and a factor of 10 for the use of an LEL instead of a NOEL. The PADI will be reevaluated when the toxicity and residue chemistry data required by this document, as listed in table A, are received and evaluated.

Utilizing the published tolerances, the Tolerance Assessment System (TAS) routine analysis yielded a theoretical maximum residue contribution (TMRC) value for the U.S. population that was 284 percent of the PADI when calculated using 100 percent of registered crops treated. After adjustment for percent of crop treated and an anticipated residue value of 0.01 ppm for milk, the calculated dietary exposure to ethephon for the U.S. population dropped to 40 percent of the PADI. For nonnursing infants and for children 1-6 years of age, the adjusted values were 122 and 95 percent of the PADI, respectively.

D. Environmental Fate

Available data are insufficient to fully assess the environmental fate of ethephon.

The only partially acceptable data available were two leaching studies which provided conflicting results regarding the leaching rates (in one study ethephon is a leacher and the other study demonstrates that ethephon is not a leacher). In one of these studies, ethephon was found to be of low to moderate mobility in soils ranging in texture from loamy sand, peat and silt loam based on soil thin layer chromatography (TLC) tests. Therefore, the potential for contamination of ground water appears to be low to moderate. Data are required on leaching, volatility, and hydrolysis of ethephon to characterize the potential to reach ground water.

E. Hazard Assessment For Terrestrial and Aquatic Organisms

1. Aquatic Organisms

Available acute toxicity data indicate that ethephon is slightly toxic to all fish species tested. The Guidelines requirements for freshwater fish acute LC_{50} data with technical ethephon have been met. The LC_{50} for freshwater fish results from two 96-hour studies using the technical grade material and the LC_{50} values follow:

Species	% ai	LC_{50} mg/L
Bluegill	21.6	67
Bluegill	21.5	> 180
Bluegill	71.3	221.7
Bluegill	92	106
Rainbow Trout	21.6	77
Rainbow Trout	71.3	254.5
Rainbow Trout	92	> 110

Ethephon is practically non-toxic to aquatic invertebrates (daphnids) with an LC_{50} value of > 180 mg/L. Technical ethephon is slightly toxic on an acute basis to grass shrimp with an LC_{50} of 160 to >370 mg/L and mud crabs with an LC_{50} of 167 to >370 mg/L. There are no data available to characterize the toxicity of ethephon to either estuarine/ marine fish or mollusks. Because the LC_{50} values of freshwater (93 to 165 mg/L) and saltwater (160 to >370) invertebrates indicate similar toxicities for fresh and saltwater classes of animals, and because of low toxicity to freshwater fish, the Agency will waive the requirement for estuarine/marine fish testing. However, the Guidelines requirements for testing mollusks are not satisfied, and are required.

2. Terrestrial Organisms

There is no evidence to suggest that the use of ethephon has resulted in avian or mammalian mortality or has affected their population levels.

The data indicate that technical ethephon is slightly toxic on an acute oral basis to bobwhite quail, and on a subacute dietary basis is sightly toxic to bobwhite quail and mallard ducks. The acute oral LC_{50} in bobwhite quail is from 596 to 804 mg/kg. The acute oral LC_{50} is 3750 ppm for mallard duck and >2160 ppm in bobwhite quail. The average acute oral toxicity for formulated products is >10,000 ppm in bobwhite quail, or practically non-toxic.

No avian reproduction study was available for evaluation; the study is not being required at this time because the use patterns are not anticipated to subject birds to repeated exposure during the breeding season.

There is sufficient information to characterize ethephon as relatively nontoxic to honeybees.

3. Plant Protection

No plant protection studies were available for evaluation: All Tier I data on Non-Target Area Phytotoxicity are required for pesticides used in forests and natural grasslands. In addition, Aquatic Plant Growth data are required as special testing (Section 70-1) for the cranberry use because that use involves application of ethephon in close proximity to aquatic habitats. Thus, Tier I testing is required to assess the potential hazard to both terrestrial and aquatic nontarget plants.

F. Endangered Species

No precautionary labeling is required at this time. However, the Agency does not have adequate environmental fate data to judge the potential risk to nontarget plant species. The Agency will reassess the risk to nontarget plant species when the environmental fate data required by this document (listed in table A) are submitted and have been evaluated.

G. Product Chemistry Evaluation

Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be

resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. As discussed above, the Agency has identified impurities which may be present in in ethephon and is requiring data to ascertain the extent of contamination.

IV. REGULATORY POSITION

A. Regulatory Positions and Rationales

Based on review and evaluation of all available data and other relevant information on ethephon, the Agency has made the following determinations:

1. A Special Review is not being initiated at this time.

Rationale:

If a pesticide meets or exceeds any of the criteria specified in 40 CFR 154.7, a Special Review of the chemical may be conducted. Agency review and evaluation of the available data indicate that none of the criteria specified have been met or exceeded by the currently registered use patterns for ethephon.

2. The Agency will not require restricted use classification for ethephon end-use products.

Rationale:

Although ethephon meets one of the criteria for restricted use classification because of its corrosivity to the eyes and skin, label restrictions requiring protective clothing will be adequate to address the hazard without imposition of the restricted use classification. See section IV B of this document for the required label statements.

3. The Agency is deferring decisions concerning ethephon's potential for contaminating ground water until information on its environmental characteristics and fate have been submitted and reviewed.

Rationale:

The Agency is unable to assess the potential for ethephon to contaminate ground water because the environmental fate of this chemical is largely unknown. Preliminary data indicate that unaged ethephon may be mobile in loamy sand, silt loam and peat soils, and immobile in sandy clay loam soils. Additional data are needed in order to assess the environmental fate of ethephon. When these data have been received and evaluated, the Agency will assess ethephon's potential for ground water contamination and will determine whether any regulatory action is necessary.

4. The Agency has identified certain data that will receive immediate review when submitted.

Rationale:

Certain data are essential to the Agency's assessment of this pesticide and its uses and/or may trigger the need for further studies which should be initiated as soon as possible. The following studies have been identified to receive priority review as soon as they are received by the Agency:

Residue Chemistry: 158.240	
Metabolism (animal)	171-4
Toxicology: 158.340	
21-day Dermal	82-2
21-day Smoke Inhalation	82-X

General Metabolism	85-1
Chronic Toxicity Rodent	83-1*
Oncogenicity data	83-2*
Environmental Fate 158.290	
Leaching Adsorption/Desorption	163-1
Vegetative Vigor	122-1
Seedling Germination and Seedling Emergence	122-1
Aquatic Plant Growth	122-1

*These studies may be upgraded or they will have to be repeated.

5. The Agency has determined that foliar and soil dislogeable residue data are required to establish reentry intervals for all crops. An interim reentry interval of 24 hours is being imposed for all crops until final reentry reentry intervals are established.

Rationale:

An interim 24-hour reentry interval is being imposed for the agricultural uses of ethephon until adequate data have been submitted and evaluated. Interim reentry intervals are being imposed to provide worker protection while data needed to establish reentry intervals are being generated.

6. Pre-harvest intervals are required on product labeling for a variety of currently registered use sites.

Rationale:

The ethephon product labels do not specify pre-harvest intervals (PHIs) for many crops, but include recommended treatment-to-harvest intervals based on efficacy rather than on residue data. In addition, data indicate that residues in or on some of the commodities increase over time then decline. Therefore, a PHI must be proposed based on the residue data for the following crops:

Peppers, cucumbers, melons, tangerines, apples, cherries, Blackberries/boysenberries, cranberries, grapes, filberts, walnuts, barley, wheat, wheat forage, hay and straw, coffee beans, Cottonseed, figs, guavas, pineapples, and sugarcane.

Interim PHI's based on the existing data are required on end-use product labels (refer to section D of this document).

7. The Agency is requiring data on animal metabolism as well as storage stability studies and residue studies for poultry and eggs. In order to remain in compliance with FIFRA, registrants must do one of the following:

a. Submit data which demonstrate that no residues remain in eggs and poultry as a result of feeding treated commodities;

b. Propose tolerances and provide appropriate supporting data for residues in poultry tissues and eggs.

Rationale:

Ethephon residues may be found in agricultural commodities used for poultry feed. If residue-bearing commodities are fed to poultry, residues may be present in poultry and eggs (which may be used for human food). However, no tolerance exist for these foods. In order to avoid unauthorized levels of ethephon residues, it must be demonstrated that residues will not be found in poultry and eggs, or tolerances must be established.

8. Additional residue data, including processing data, must be submitted for the following raw agricultural commodities: peppers, tomatoes, cucumbers, melons, lemons, tangerines, apples, cherries, blackberries, boysenberries, blueberries, cranberries, grapes, filberts, walnuts, barley (wheat data may substitute), wheat, (and wheat straw), coffee beans, cotton seed, figs, guavas, pineapples, sugarcane, and tobacco. For tobacco, pyrolysis data must be submitted. If residues concentrate in any of the processed products, the appropriate food additive tolerance(s) must be proposed. Specific data requirements may be found in the data tables.

Rationale:

The available data are inadequate to support existing tolerances for these commodities.

9. The Agency is requiring the proposal of either a tolerance for sugarcane forage or a grazing prohbition for sugarcane forage.

Rationale:

Since forage is a raw agricultural commodity of sugarcane, a tolerance must be establish for it. However, no tolerance exists. Residue data are needed to establish a tolerance and a pregrazing interval.

10. The Agency has determined that the following revisions in the tolerances listed in 40 CFR 180.300 and 21 CFR 193.186 are necessary.

- The designation "N" (negligible) must be deleted from all tolerances entries.
- The commodity "pineapple fodder" must be deleted from 40 CFR 180.300.
- The tolerance for guava must be added to 40 CFR 180.300.
- The tolerance for raisins must be added to 21 CFR 193.186.

Rationale:

- The Agency no longer accepts the concept of "negligible" residues, therefore the designation will no longer be used.
- The tolerance for residues in or on pineapple fodder is inappropriate because this commodity is not a raw agricultural commodity but a processed animal feed item.
- The tolerance for guava should be published under 40 CFR 180.300. Although a tolerance was published in the 1980 (45 FR 47147), the listing of this tolerance does not appear in the Code of Federal Regulations. Correction of this omission will make the CFR current for ethephon.
- A food additive tolerance for raisins was established in 21 CFR 193.186 but does not appear in current issues of the Code of Federal Regulations. A correction would make the CFR current for ethephon.

11. Product chemistry and residue data are required depicting residues of monochloroacetic acid in or on food and feed commidities following registered applications of ethephon.

Rationale:

Monochloroacetic acid is a potential degradate of certain impurities in the ethephon technical product. Because of its extreme toxicity, it is currently regulated under 21 CFR 189.155 ("Food containing any added or detectable level of monochloroactic acid is deemed to be adulterated..."). Therefore, the Agency deems it necessary to determine whether monochloroacetic acid is likely to occur in food as a result of direct treatment with ethephon.

12. The Agency has identified 2-chloroethanol as a contaminant of toxiclogical concern. The Agency is requiring data to assess the extent of contamination with this substance. Additionally, the Agency is requiring that manufacturing use products bear a label statement advising users to store and use the product in well-ventilated areas. The label statement appears in Section D. 3. of this document.

Rationale:

2-Chloroethanol has been found in technical ethephon products. This substance is extremely toxic through the inhalation route. More data are required to assess the extent of contamination with 2-chloroethanol. The impurity could pose a hazard when technical or manufacturing use products are stored or used under conditions that permit 2-chloroethanol vapors to accumulate to hazardous levels. Storage or use of technical or manufacturing use ethephon products in wellventilated areas would reduce the risk of posed by 2-choroethanol. Accordingly, the Agency is that the labels of manufacturing use products be revised to state that the product should be stored and used in well-ventilated areas.

13. While the data gaps are being filled, currently registered manufacturing-use products and end-use products containing ethephon as the sole active ingredient may be sold, distributed, formulated, and used in the United States, subject to the terms and conditions specified in this Standard. Registrants must provide or agree to develop additional data, as specified in Appendix I to maintain existing registrations.

The Agency will issue registrations for substantially similar products and new uses will be issued after considering the effects on the theoretical maximum residue contribution (TMRC) and the maximum permissable intake (MPI).

Rationale:

Section 6 of FIFRA authorizes the Administrator to cancel a pesticide registration if he determines that the pesticide will cause unreasonable adverse effects on the environment. Based on available data, the Administrator has not made such a determination as to ethephon. The Administrator has authority under FIFRA sections 3(c)(2)(B) and 3(c)(7) to require registrants and applicants for registration to provide data needed to support new or continuing registrations.

Issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated and the Agency will determine if the data will affect the registration of ethephon.

B. Criteria For Registration

To be registered or reregistered under this Standard, products must contain ethephon as the sole active ingredient; bear required labeling; and conform to the product composition, and use pattern requirements listed in this section.

C. Acceptable Ranges and Limits

1. Product Composition Standard

To be registered or reregistered under this Standard, manufacturing-use products (MPs) must contain ethephon as the sole active ingredient. Each MP formulation proposed for registration or reregistration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as impurities found at greater than 0.1 percent.

2. Acute Toxicity

The Agency will consider registration of technical grade and manufacturing-use products containing ethephon provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns

To be registered under this Standard, technical grade or manufacturing-use products containing ethephon may be labeled for formulation into end-use products registered only for the uses listed in the EPA compendium of acceptable uses. This compendium lists all registered uses, as well as approved maximum application rates and frequencies and is available through the Freedom of Information Office.

D. Required Labeling

In order to remain in compliance with FIFRA, products must bear appropriate labeling as specified in 40 CFR 156.10 and in this Standard, or must be revised to conform to those specifications. Appendix II contains information on labeling requirements.

No pesticide product containing ethephon may be released for shipment by the registrant or producer after September 30, 1989 unless the product bears an amended label which complies with the requirements of this Standard.

No pesticide product containing ethephon may be distributed or sold after September 30, 1990 unless the product bears an amended label which complies with the requirements of this Standard.

The following specific information must appear on the labeling in order for porducts to remain in compliance with FIFRA:

1. Ingredients Statement

The ingredient statement shall list the active ingredient as:

ACTIVE INGREDIENT:

Ethephon [(2-chloroethyl) phosphonic acid]: ____________ %

2. Use Pattern Statement

All manufacturing-use products must state that they are intended for formulation into end-use products for acceptable use patterns. Labeling must specify sites, which are listed in Use Patterns, Section C.3. However, no use may be included on the label where the registrant fails to agree to comply with data requirements in Table A for that use pattern.

3. The Following Must Appear on MUP Labels

"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water unless this product is specifically identified and addressed in a NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

"Technical grade ethephon must be stored and used in ventilated areas only."

4. The Following Must Appear on EP Labels

"Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not contaminate water when disposing of equipment washwaters.'

"Mixers, loaders and applicators must wear a full face shield, long trousers, long sleeved shirt, gloves, and boots to avoid as much skin and eye contact as possible."

"Do not enter treated fields within 24 hours after application unless protective clothing is worn."

The following interim pre-harvest intervals (PHI) must be included on end use product labels for the raw agricultural commodities listed. These interim PHI's may be revised after the required field residue data have been submitted and evaluated.

Apples, minimum 7 days; barley, 40 days; blackberries and blueberries, 42 days; cherries, minimum 7 days; coffee beans, 14 days; cotton, 14-21 days; cranberries, 17-21 days; cucumbers, 17-21 days; figs, 14 days; filberts, 7 days; grapes, 14 days; guavas, 7 months; melons, 2 days; peppers, 14 days; pineapples, 2 days; tangerines, 5-10 days; tomatoes, 14-20 days for processing and 3-6 days for fresh market in California only; walnuts, 5-10 days; wheat, 40 days.

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submittal or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.
2. The data requirements listed in Tables A and B[2]
3. The labeling requirements specified for manufacturing use products in Section IV.
4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

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[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by an end use producer who is eligible for the generic data exemption for that active ingredient.

Table C lists product-specific data applicable to end use products. The Agency has decided that, in most cases, it will not require the submittal of product-specific data for end use products at this time. Therefore most Registration Standards do not contain a Table C.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

1. The data requirements listed in Table A.

2. The labeling requirements specified for manufacturing use products in Section IV.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the generic data exemption[3], the data requirements listed in Table C.

3. If not eligible for the generic data exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

1. If not eligible for the generic data exemption, the data requirements listed in Tables A and C.

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[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the generic data exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to the data requirements in Table A.

2. If eligible for the generic data exemption, the data requirements listed in Table C.

3. The labeling requirements specified for end use products in Section IV.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and § 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

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[4] Registrations granted after issuance of this Standard will be conditioned upon submittal or citation of the data listed in this Registration Standard.

If you are not now eligible for a generic data exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Generic Data Exemption Statement.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submittal or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will

submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submittal. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number, as part of your 90-day response. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submittals by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data. The Agency will respond in writing to your request for a waiver.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Registrant Requests Regarding Data Requirements and Agency Responses

All requests for modification of data requirements (inapplicability, waiver), approval of protocols or protocol changes, or time extensions must be submitted in writing. The original requirement remains in effect unless the Agency has notified you in writing that it has agreed to a change in the requirement. While being considered by the Agency, such requests for changes in the requirements do not alter the original requirements or extend the time allowed for meeting the requirement.

F. Test Protocols and Standards

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing. All testing must be conducted in accordance with applicable Good Laboratory Practices regulations in 40 CFR Part 160.

The Pesticide Assessment Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

G. Procedures for requesting a change in test protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submittal of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols. The Agency will respond in writing to your request for protocol approval or change.

H. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time.

EPA will view failure to request an extension before the data submittal response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. The Agency will respond in writing to any requests for extension of time.

I. Data Format and Reporting Requirements

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986). All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submittal requirement.

J. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision for the registrant is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D through J. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMITTAL OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 156.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling language specific to products containing this pesticide is specified in Section IV.D of this Registration Standard. Responses to this Registration Standard must include draft labeling for Agency review.

Labeling must be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. Draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

If you fail to submit revised labeling as required, which complies with 40 CFR 156.10 and the specific instructions in Section IV.D., EPA may seek to cancel the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMITTAL

All submittals in response to this Registration Standard must be sent to the following address:

Office of Pesticide Programs
OPP Mailroom (TS-767C)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

Attn: ETHEPHON Registration Standard

All submittals in response to this Registration Standard are non-fee items, including 90-day responses, protocols and waiver requests, data, and revised labeling. Submittals must be clearly identified as being in response to the Registration Standard. Under no circumstances may Registration Standard responses be combined with other types of filings for which fees are required.

A. Manufacturing Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit for each product subject to this Registration Standard:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months from receipt of this document you must submit:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Three copies of draft labeling, including the container label and any associated supplemental labeling.

d. Product Specific Data Report (EPA Form 8580-4).

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

2. Within 9 months of receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the time frames set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately

notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from receipt of this document you must submit:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

D. End Use Products containing the subject active ingredient as one of multiple active ingredients

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from the receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

E. Intrastate Products

Applications for full Federal registration of intrastate products were required to be submitted no later than July 31, 1988. Unless an application for registration was submitted by that date, no product may be released for shipment by the producer after July 31, 1988.

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

> YES - EPA has data in its files that satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.
>
> PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.
>
> NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A. GENERIC DATA REQUIREMENTS FOR THE TECHNICAL GRADE OF THE ACTIVE INGREDIENT ETHEPHON

Data Requirement	Test Substance[1]	Does EPA Have Data2	Bibliographic Citation3	Must Additional Data Be Submitted?	Timeframe For Submission
158 Subpart C Product Chemistry					
Product Identity and Composition					
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	No	N/A	Yes[4]	6 months
61-3 - Discussion of Formation of Impurities	TGAI	No	N/A	Yes[5]	6 months
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis of Product Samples	TGAI	No	N/A	Yes[6]	12 months
Physical and Chemical Characteristics					
63-2 - Color	TGAI	No	N/A	Yes[7]	6 months
63-3 - Physical State	TGAI	No	N/A	Yes[7]	6 months
63-4 - Odor	TGAI	No	N/A	Yes[7]	6 months
63-5 - Melting Point	TGAI	No	N/A	Yes[7,8]	6 months
63-6 - Boiling Point	TGAI	No	N/A	Yes[7,9]	6 months
63-7 - Density, Bulk Density or Specific Gravity	TGAI	No	N/A	Yes[7]	6 months
63-8 - Solubility	TGAI or PAI	No	N/A	Yes[7]	6 months
63-9 - Vapor Pressure	TGAI or PAI	No	N/A	Yes[7]	6 months
63-10 - Dissociation Constant	TGAI or PAI	No	N/A	Yes[7]	6 months
63-11 - Octanol/Water Partitioning Coefficient	PAI	No	N/A	Yes[7,10]	6 months
63-12 - pH	TGAI	No	N/A	Yes[7,11]	6 months
63-13 - Stability	TGAI	No	N/A	Yes[7]	6 months
Other Requirements:					
64-1 - Submittal of Samples	N/A	N/A	N/A	No	

TABLE A. GENERIC DATA REQUIREMENTS FOR THE TECHNICAL GRADE OF THE ACTIVE INGREDIENT ETHEPHON

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[1] TGAI = technical grade of the active ingredient. PAI = purified active ingredient.

[2] Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

[3] Data must be submitted within the timeframe, based on the date of this Guidance Document.

[4] Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material used in the manufacture of each product must be provided, along with information regarding the properties of those materials.

[5] A detailed discussion of all impurities that are or may be present at $\geq$ 0.1 percent, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted.

[6] Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which certified limits are required. Complete validation data (accuracy and precision) must be submitted for each analytical method used.

[7] Physicochemical characteristics (color, physical state, odor, melting point, boiling point, specific gravity, solubility, vapor pressure, dissociation constant, partition coefficient, pH, and stability) as required in 40 CFR 158.120 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, must be submitted.

[8] Data needed if the technical chemical is a solid at room temperature.

[9] Data required if the technical product is a liquid at room temperature.

[10] Data required if the technical product is organic and nonpolar.

[11] Data required if the test substance is dispersible in water.

TABLE A. GENERIC DATA REQUIREMENTS FOR ETHEPHON

Data Requirement	Test Substance[1]	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Submission[2]
158.240 Residue Chemistry					
171-2 - Chemical Identity[3]	TGAI				
171-3 - Directions for use	TEP	Yes		No	
171-4 - Nature of the residue (Metabolism) - Plants	PAIRA	Yes	00038793, 00038796, 00054018, 00054021, 00067489, 00081783, 00088983, 00097422, 00108993, 00116123, 00117893, 00121613, 00122410	No	
171-4 - Nature of the residue (Metabolism) - Livestock	PAIRA and plant metabolites	Partially	00118508, 00141506, 00165339	Yes[4,5]	18 months

TABLE A. GENERIC DATA REQUIREMENTS FOR ETHEPHON (Continued)

Data Requirement	Test Substance[1]	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Submission[2]
171-4 - Residue analytical methods	TGAI and metabolites	Partially	00030190, 00036500 00038795, 00038797, 00038880, 00038881, 00042977, 00041465, 00047911, 00047913, 00053149, 00103287, 00108992, 00116123, 00117893, 00121613, 00122410, 00122421, 00122433, 00122435, 00123237, 00128726, 00142265, 00145613,	Yes[6]	15 months
171-4 - Storage stability	TEP and metabolites	Partially	00151127	Yes[7]	18 months
171-4 - Magnitude of the residue in plants					
Fruiting Vegetables - Peppers	TEP	Partially	00061719, 00121613	Yes[8,9]	6 months
- Tomatoes	TEP	Partially	00121613	Yes[10] Yes[11]	18 months 24 months

TABLE A. GENERIC DATA REQUIREMENTS FOR ETHEPHON (Continued)

Data Requirement	Test Substance[1]	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Submission[2]
Cucurbit Vegetables					
- Cucumbers		Partially	PP#9E2225(098344)	Yes[12,9]	6 months
- Melons	TEP	Partially	00117893	Yes[13,9]	18 months
- Pumpkins	TEP	Yes	00122717	Reserved[9]	
Citrus Fruits					
- Lemons	TEP	Partially	00121613	Yes[14,9] Yes[15]	18 months 24 months
- Tangerines	TEP	Partially	00121613	Yes[16]	18 months
Pome Fruits					
- Apples	TEP	Partially	00061717, 00108992, 00123222	Yes[17,9] Yes[18]	6 months 24 months
Stone Fruits	TEP				
- Cherries (sweet and sour)		Partially	00081782, 00136287	Yes[19,9]	6 months
Small Fruits and Berries					
- Blackberries and Boysenberries	TEP	Partially	00121613	Yes[20]	18 months
- Blueberries	TEP	Partially	00121613	Yes[21,9]	6 months
- Cranberries	TEP	Partially	00121613	Yes[22]	18 months

TABLE A. GENERIC DATA REQUIREMENTS FOR ETHEPHON (Continued)

Data Requirement	Test Substance[1]	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Submission[2]
- Grapes	TEP	Partially	00053150, 00080482, 00121613	Yes[23] Yes[24]	18 months 18 months
Tree Nuts					
- Filberts	TEP	Partially	00038797	Yes[25,9]	6 months
- Macadamia nuts	TEP	Yes	00128726	Reserved[9]	
- Walnuts	TEP	Partially	00038795, 00117752	Yes[26,9]	6 months
Cereal Grains					
- Barley	TEP	Partially	00103287	Yes[27,9]	18 month
- Wheat	TEP	Partially	00103287	Yes[28,9] Yes[29]	18 month 24 month
Forage, Fodder, and Straw of Cereal Grains					
- Barley straw	TEP	Partially	00103287	Yes[30]	18 months
- Wheat straw	TEP	Partially	00103287	Yes[31,9]	18 months
Miscellaneous Commodities					
- Coffee beans	TEP	Partially	00041465	Yes[32] Yes[33] Yes[34]	18 months 24 months 6 months

TABLE A. GENERIC DATA REQUIREMENTS FOR ETHEPHON (Continued)

Data Requirement	Test Substance[1]	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Submission[2]
- Cottonseed	TEP	Partially	00030190, 00122423	Yes[35] Yes[36]	18 months 6 months
- Figs	TEP	Partially	00036500	Yes[37,9] Yes[38]	6 months 24 months
- Guavas	TEP	Yes	PP#9E2262	Yes[39,9]	18 months
- Pineapples	TEP	Partially	00040268, 00040269, 00054022, 00116123, 00122452, 00123222	Yes[40] Yes[41]	18 months 24 months
- Sugarcane	TEP	Partially	00032573, 00145613	Yes[42] Yes[43]	6 months 24 months
- Tobacco	PAIRA	Partially	00122410	Yes[44]	18 months
171-4 - Magnitude of residue in Meat/Milk/Poultry/Eggs	TGAI	Partially	00083773, 00100517, 00121613	Yes[45]	18 months

TABLE A. GENERIC DATA REQUIREMENTS FOR ETHEPHON (Continued)

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[1] Test substance: TGAI = technical grade of the active ingredient; PAI = purified active ingredient; PAIRA = purified active ingredient, radiolabeled; TEP = typical end-use product; EP = end-use product.

[2] Data must be submitted within the indicated timeframe, based on the date of this Guidance Document.

[3] The same chemical identity data are required as under 158.120, with emphasis on impurities of toxicological concern that constitute residue problems. Refer to Product Chemistry Data Requirement tables.

[4] A poultry metabolism study must be submitted. Animals must be dosed orally for a minimum of 3 days with [UL-^{14}C at a level sufficient to make residue identification and quantification possible. Eggs must be collected twice a day during the dosing period. Animals must be sacrificed within 24 hours of the final dose. The distribution and identity of ^{14}C-residues (including ^{14}C-residues incorporated into natural products) must be determined in eggs, liver, kidney, muscle, and fat. Samples from these studies must also be analyzed using the Union Carbide-animal method [MRID # 00142265] to ascertain that this method is capable of adequately recovering and identifying all residues of toxicological concern.

[5] Data depicting the nature of ethephon residues in swine are also required unless the metabolism in ruminants and poultry does not differ from that in rats.

[6] Representative plant samples, ruminant tissues, and milk bearing residues of ethephon must be subjected to analysis by PAM Vol. I methods 211.1, 212.1, 231.1, 232.1, and 252. Protocols for multiresidue methods I, II, III, and IV are available from the National Technical Information Service under Order No. PB 203734/AS.

[7] Samples bearing field-weathered residues or fortified samples of one representative commodity from each crop group and representative animal commodities (meat, milk, eggs) must be analyzed immediately after harvest or fortification and again after storage intervals that are equivalent to those reflected in all previously submitted and currently requested data. Storage conditions for the samples must also reflect those in previously submitted and currently requested data. The chosen intervals must allow for unforseen delays in sample storage. In laboratory tests using fortified samples, the pure active ingredient and pure metabolites (if necessary) must be used. However, if field weathered samples are used, the test substance must be a typical end-use product. For additional guidance on conducting storage stability studies, the registrant is referred to an August, 1987 Position Document on the Effects of Storage on Validity of Pesticide Residue Data available from NTIS under order no. PB88112362/AS.

TABLE A. GENERIC DATA REQUIREMENTS FOR ETHEPHON (Continued)

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[8] The registrant must amend all pertinent product labels to specify a PHI. The available data indicate that a PHI of 5 days or longer would be appropriate.

[9] Additional residue data may be required on receipt of the storage stability data required in footnote # 7.

[10] Data must be submitted depicting residues of ethephon and monochloroacetic acid in or on tomatoes resulting from a single foliar application of the 2 lb/gal SC/L formulation at 1.6 lb ai/A, in 20 gal/A using ground equipment and, in seperate tests, in 10 gal/A using aerial equipment. The data must depict the increase and decline of residues over a suitable range of posttreatment intervals. The registrant must propose a PHI based on these data. The tests must be conducted in CA (75%) and FL (8%), states that represented ca. 80 percent of 1985 total U.S. tomato production.

[11] Data must be submitted depicting the potential for concentration of residues in juice, dried pomace, puree, and catsup processed from tomatoes bearing measurable weathered residues. If residues concentrate in any processed fraction, an appropriate food/feed additive tolerance must be proposed.

[12] The registrant must propose a PHI based on the minimum interval expected between the second application (5 days after the plants are at the four-leaf stage) and harvest. The available data indicate that a PHI of 17 days or longer would be appropriate.

[13] Data must be submitted depicting ethephon and monochloroacetic acid residues in or on cantaloupes harvested 2 days (or a PHI proposed by the registrant) following aerial application of the 2 lb/gal SC/L formulation at 0.75 lb ai/A. Tests must be conducted in TX. The registrant must propose a PHI for application of ethephon to cantaloupes; the available data indicate that, following application using ground equipment, a PHI of 2 days would be appropriate.

[14] The registrant must either (i) provide documentation that lemons will not be shipped or sold for ≥ 2 weeks after treatment, or (ii) submit data depicting ethephon and monochloroacetic acid residues in or on lemons immediately after a single postharvest application of the 2 lb/gal SC/L formulation at 0.83 lb ai/100 gal of water/100-130 tons of fruit.

TABLE A. GENERIC DATA REQUIREMENTS FOR ETHEPHON (Continued)

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[15] Data must be submitted depicting the potential for concentration of ethephon residues in dried pulp, oil, and molasses during the processing of treated lemons bearing measurable residues. If the data indicate a potential for residue concentration in any of these commodities, the registrant must propose an appropriate food/feed additive tolerance.

[16] Data must be submitted depicting ethephon and monochloroacetic acid residues in or on whole tangerines harvested at regular intervals following a single foliar application of the 2 lb/gal SC/L formulation at 1.25 lb ai/A in 400 gallons of water/A. The data must depict levels of ethephon residues and a PHI must be proposed based on the requested data. Tests must be conducted in FL.

[17] The registrant must propose a PHI. The available data indicate that a PHI of 7 days would be appropriate.

[18] Data must be submitted depicting the potential for concentration of residues in dried pomace from treated apples bearing measurable weathered residues. If the data indicate a potential for residue concentration in this commodity, the registrant must propose an appropriate feed additive tolerance.

[19] The registrant must amend all pertinent labels to include a PHI based on the minimum interval expected between application and harvest. The available data indicate that a PHI of 7 days or longer would be appropriate.

[20] Data must be submitted depicting residues of ethephon and monochloroacetic acid in or on blackberries or boysenberries resulting from a single foliar application of the 2 lb/gal SC/L formulation at 2.18 lb ai/A, in 175 gal/A using ground equipment. The data must depict the levels of residues over a suitable range of post-treatment intervals. The registrant must propose a PHI based on these data. The tests must be conducted in OR which accounted for ca. 80 percent of 1982 U.S. blackberry production. A tolerance for residues in or on boysenberries must be proposed.

[21] The registrant must propose a PHI for application of ethephon to blueberries. The available data indicate that a 7-day PHI would be appropriate.

[22] Data are required depicting residues of ethephon and monochloroacetic acid in or on cranberries harvested at regular intervals following a single foliar application of the 2 lb/gal SC/L formulation at 1.5 lb ai/A applied in 200 gal/A using ground equipment, and in 5 to 30 gal/A using aerial equipment, in separate tests. The data must depict the level of residues over a suitable range of posttreatment intervals. The registrant must propose a PHI based on these data. Tests must be conducted in MA, NJ, and WI.

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[23] Data must be submitted depicting residues of ethephon and monochloroacetic acid in or on grapes and raisin waste harvested at regular intervals following a single foliar application of the 2 lb/gal SC/L formulation at 0.5 lb ai/A. Data must depict the level of residues over a suitable range of posttreatment intervals. Tests must be conducted in CA where this use is registered. The registrant must propose adequate tolerance revisions (if necessary) for residues of ethephon in or on grapes and raisin waste based on appropriate supporting residue data. In addition, the registrant must propose a PHI based on the requested residue data.

[24] When an appropriate tolerance for residues in or on grapes is determined, food/feed additive tolerance at 4x must be established for grape juice and dried grape pomace, and a food additive tolerance at 7x must be established for raisins.

[25] The registrant must amend all pertinent labels to include a PHI based on the minimum interval expected between application and harvest. The available data indicate that a PHI of 7 days or longer would be appropriate.

[26] The registrant must amend all pertinent labels to include a PHI based on the minimum interval expected between application and harvest. The available data indicate that a PHI of 5 days or longer would be appropriate.

[27] The registrant must amend all pertinent product labels to include a PHI. The available data (reflecting ground application) indicate that a PHI of 40 days would be appropriate.

[28] Residue data must be submitted of ethephon and monochloroacetic acid in or on wheat grain harvested following one aerial application of a representative SC/L formulation at 0.5 lb ai/A in 3 gal/A. Tests must be conducted in KS (18%) or CO (6%), ND (13%) or NM (6%), and in WA (5%) which collectively represent the major wheat growing areas in the United States and ca. 50 percent of the 1985 U.S. wheat production The registrant must amend all pertinent product labels to specify a PHI based on the residue data. The available data (from tests using ground application indicate that a PHI of 40 days would be appropriate.

[29] Data must be submitted depicting concentration of residues in middlings and wheat grain dust resulting from the processing of wheat grain bearing measurable weathered residues. If the data indicate a potential for concentration of residues in grain dust, an appropriate feed additive tolerance must be proposed.

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[30] Data required to support the tolerance for residues in or on wheat straw will be translated to barley straw.

[31] Data must be submitted depicting residue of ethephon and monochloroacetic acid in or on wheat straw harvested following one aerial application of a representative SC/L formulation at 0.5 lb ai/A in 3 gal/A. Tests must be conducted in KS (18%) or CO (6%), ND (13%) or MN (6%), and in WA (5%) which collectively represent the major wheat growing areas in the United States and ca. 50 percent of the 1985 U.S. wheat production The registrant must amend all pertinent product labels to specify a PHI based on the residue data. The available data (from tests using ground application) indicate that a PHI of 40 days would be appropriate.

[32] Data must be submitted depicting ethephon and monochloroacetic acid in or on green coffee beans harvested at regular intervals following a single foliar application of the 4 lb/gal SC/L formulation at 600 mg/plant to a 4 meter coffee plant. Tests must be conducted in Guatemala, Costa Rica, and Brazil which accounted for the majority of the 1985 coffee bean importation to the U.S. from North and South America. The registrant must amend all pertinent product labels to specify a PHI.

[33] Data must be submitted depicting the potential for concentration of residues in roasted beans and instant coffee processed from beans bearing measurable weathered residues. If residues concentrate in any of these processed commodities, an appropriate food additive tolerance must be proposed.

[34] The registrant must submit an English translation of all labels bearing directions for use of ethephon on coffee grown for importation into the U.S.

[35] Data must be submitted depicting residues of ethephon and monochloroacetic acid in or on cottonseed harvested 14 days after the last of two applications (one application made at 2 lb ai/A when 50 percent of the bolls are open and the second treatment made at 1 lb ai/A 4 days later) of the 2 lb/gal FLC and a representative EC formulation (each in separate tests) applied with aerial equipment in 2 gal. water/A and, in separate tests, using ground equipment in 5 gal. water/A. The data must depict the posttreatment interval at which residues decline. Tests must be conducted in AZ (7%), AR (5%), CA (23%), GA (3%), MS (12%), NM (< 1%), OK (2%), and TX (29%) which collectively accounted for ca. 80 percent of 1985 U.S. cotton production. The registrant must propose an appropriate PHI based on the requested residue data.

TABLE A. GENERIC DATA REQUIREMENTS FOR ETHEPHON (Continued)

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[36] When an appropriate tolerance for residues in or on cottonseed is determined, food/feed additive tolerances at 6x in meal, 2x in refined oil, and 4x in soapstock must be proposed.

[37] The registrant must amend all pertinent product labels to specify a PHI. Available data indicate that a PHI of 14 days or longer would be appropriate.

[38] Data must be submitted depicting the potential for concentration of residues in dried figs processed from fresh figs bearing measurable weathered residues. If residues concentrate in dried figs, an appropriate food additive tolerance must be proposed.

[39] The registrant must submit data regarding the gal. water/A rate used in previously submitted field trials (PP#9E2262) and a PHI of $\geq$ 7 months must be proposed. If the gal. water/A data are not available or at least 250 gal/A were not applied, data depicting residues of ethephon and monochloroacetic acid in or on guavas harvested following a postharvest application made at 3.13 lb ai/250 gal. water/A must be submitted. The finished spray must contain a nonionic surfactant. A PHI must be proposed based on the residue data. The tests must be conducted in HI where this use is registered. Alternatively, the registrant may elect to cancel this use permitted under EPA SLN No. HI800012.

[40] Data must be submitted depicting residues of ethephon and monochloroacetic acid in or on pineapple fruit and forage harvested at regular intervals following the last of two foliar applications of a representative SC/L formulation at 1.5 lb ai/A, one application made to foliage 6 to 8 months prior to harvest and one late-season application to plants bearing immature fruit. The data must depict the posttreatment interval at which residues begin to decline. The registran must amend the pertinent labels to specify a PHI and a pregrazing interval; these intervals must be reflected in the requested data. Tests must be conducted in HI, which accounts for ca. 100 percent of the U.S. total pineapple production.

[41] A processing study must be submitted depicting residues in products (bran and juice) processed from pineapples bearing measurable, weathered residues. If residues concentrate in any product, appropriate food/feed additive tolerances must be proposed.

[42] A PHI of $\geq$ 2 months must be proposed.

TABLE A. GENERIC DATA REQUIREMENTS FOR ETHEPHON (Continued)

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[43] Data must be submitted depicting the potential for concentration of residues in refined sugar processed from sugarcane bearing measurable weathered residues. If the data indicate a potential for concentration of residues, an appropriate food additive tolerance must be proposed.

[44] Pyrolysis products derived from ethephon must be characterized and the level of residue in tobacco smoke must be quantified. Weathered residues of [^{14}C]ethephon must be used for identification of pyrolysis products.

[45] Following receipt and evaluation of the required poultry metabolism data, storage stability data, and residue data for feed items, specific data requirements for livestock feeding studies will be determined.

TABLE A
GENERIC DATA REQUIREMENTS FOR ETHEPHON

Data Requirement	Test Substance[1]	use pattern	Does EPA Have Data2	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Submission
158.340 Toxicology						
ACUTE TESTING:						
81-1 - Acute Oral - Rat	TGAI	A,B,G	Yes	00029509	No	
81-2 - Acute Dermal	TGAI	A,B,G	Yes	00029510	No	
81-3 - Acute Inhalation - Rat	TGAI	A,B,G	No	-	Yes	9 months
81-4 - Eye Irritation - Rabbit	TGAI	A,B,G	No	-	No[4]	
81-5 - Dermal Irritation - Rabbit	TGAI	A,B,G	Yes	00029513	No	
81-6 - Dermal Sensitization - Guinea Pig	TGAI	A,B,G	No	-	Yes	9 months
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	A,B,G	Yes	00144559	No	
SUBCHRONIC TESTING:						
82-1 - 90-Day Feeding -						
Rodent	TGAI	A,B,G	No	-	No[5]	
Non-rodent	TGAI	A,B,G	No	-	No[6]	

TABLE A
GENERIC DATA REQUIREMENTS FOR ETHEPHON

Data Requirement	Test Substance[1]	use pattern	Does EPA Have Data2	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Submission
158.340 Toxicology (Cont.)						
82-2 - 21-Day Dermal-	TGAI	A,B,G	No	-	Yes	12 months
82-3 - 90-Day Dermal-	TGAI	A,B,G	No	-	No[7]	
82-4 - 90-Day Inhalation-	TGAI	A,B,G	No	-	No[8]	
82-5 - 90-Day Neurotoxicity-	TGAI	A,B,G	No	-	No[9]	
82-X - 21-Day Smoke Inhalation-	TGAI	A,B,G	No	-	Yes[10]	12 months
CHRONIC TESTING:						
83-1 - Chronic Toxicity -						
Rodent	TGAI	A,B,G	Partially	00060358 00144558	Yes[11]	3 Months
Non-rodent	TGAI	A,B,G	Partially		Yes[12]	3 Months
83-2 - Oncogenicity Study -						
Rat	TGAI	A,B,G	Partially	00060358 00144558	Yes[13]	3 Months
Mouse	TGAI	A,B,G	Partially	00165591	Yes[14]	3 Months
83-3 - Teratogenicity -						
Rat	TGAI	A,B,G	Yes	00063745	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR ETHEPHON

Data Requirement	Test Substance[1]	use pattern	Does EPA Have Data2	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Submission
158.135 Toxicology (Cont.)						
83-3 - Rabbit	TGAI	A,B,G	Yes	00085755	No	
83-4 - Reproduction -	TGAI	A,B,G	No	-	Yes	39 months
MUTAGENICITY TESTING						
84-2 - Gene Mutation	TGAI	A,B,G	Yes	00029515	No	
84-2 - Chromosomal Aberration	TGAI	A,B,G	Yes	00077061	No	
84-2 - Other Mechanisms of Mutagenicity	TGAI	A,B,G	No	-	Yes[15]	12 months
SPECIAL TESTING						
85-1 - General Metabolism	PAI or PAIRA	A,B,G	No	-	Yes	24 months
85-2 - Domestic Animal Safety	Choice	A,B,G	No	-	No[16]	

TABLE A
GENERIC DATA REQUIREMENTS FOR ETHEPHON

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[1] Composition: TGAI Technical Grade Active Ingredient; PAI = Pure Active Ingredient; PAIRA = Pure Active Ingredient, Radiolabelled; Choice = Choice of several test substances determined on a case-by-case basis.

[2] The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor; IP = Industrial Preservative.

[3] Unless otherwise specified, data must be submitted no later than six months after publication of this standard.

[4] Primary Eye Irritation Studies are not required for substances which are corrosive in Primary Dermal Irritation Studies. Since ethephon is corrosive, an Primary Eye Irritation Study is not required.

[5] This requirement is waived based on the submission of an acceptable chronic feeding study in the rat.

[6] This requirement is waived based on the submission of an acceptable chronic feeding study in the dog.

[7] This study is not required because existing acceptable end-uses should not result in repeated human skin contact.

[8] This study is not required because existing acceptable end-uses should not result in repeated inhalation exposure.

[9] Since the Acute Delayed Neurotoxicity study in hens showed no dose related neuro-histopathology, a study is not required.

[10] This study is required only if residues of degradation products of ethephon or ethephon residues on flue cured tobacco are greater than 0.1 ppm. However, since formal guidelines for such a study have not been developed, the registrant should consult with the Agency before performing the study.

[11] This study cannot be fully evaluated from the data available. Data on the stability of ethephon in the feed must be submitted. In addition, historical control data must be submitted on pancreatic islet cell carcinomas and adenomas in Sprague Dawley rats, preferably conducted in the testing facility conducting the original study or the study must be repeated.

TABLE A
GENERIC DATA REQUIREMENTS FOR ETHEPHON

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[12] This study cannot be fully evaluated from the data available. Data on the stability of ethephon in the feed must be submitted or the study must be repeated.

[13] See footnote 11.

[14] This study cannot be fully evaluated from the data available. Data on the stability of ethephon in the feed must be submitted. In addition, historical control data must be submitted on fibrosarcomas in the Swiss Albino mouse, preferably conducted in the testing facility conducting the original study.

[15] A study is required for gene mutation in mammalian cells.

[16] This study is not required under the current use patterns.

TABLE A
GENERIC DATA REQUIREMENTS FOR ETHEPHON

Data Requirement	Test Substance[1]	use pattern	Does EPA Have Data2	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Submission
158.290 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	PAIRA		No	-	Yes	9 months
PHOTODEGRADATION:						
161-2 - In Water	PAIRA		No	-	Yes	9 months
161-3 - On Soil	PAIRA or TGAI		No	-	Yes	9 months
161-4 - In Air	PAIRA or TGAI		No	-	Reserved[4]	
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	PAIRA	A,B,F, G,H	No	-	Yes	27 months
162-2 - Anaerobic Soil	PAIRA or TGAI	A,B	No	-	Yes[5]	27 months
162-3 - Anaerobic Aquatic	PAIRA or TGAI	G	No	-	Yes	27 months
162-4 - Aerobic Aquatic	PAIRA or TGAI	--	No	-	No[6]	
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/Desorption	PAIRA	A,B,F, G,H	No	-	Yes[7]	12 months
163-2 - Volatility (Lab)	TEP	A,B,F	No	-	Reserved[4]	
163-3 - Volatility (Field)	TEP	A,B,F	No	-	Reserved[4]	

TABLE A
GENERIC DATA REQUIREMENTS FOR ETHEPHON

Data Requirement	Test Substance[1]	use pattern	Does EPA Have Data2	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Submission
158.290 Environmental Fate (Cont.)						
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP	A,B	No	-	Yes	27 months
164-2 - Aquatic (Sediment)	TEP	—	No	-	No[6]	
164-3 - Forestry	TEP	G	No	-	Yes	27 months
164-4 - Combination and Tank Mixes	TEP	--	No	-	No[8]	
164-5 - Soil, Long-Term	TEP	A,B	No	-	Reserved[9]	
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	A,B	No	-	Yes	39 months
165-2 - Rotational Crops (Field)	TEP	A,B	No	-	Reserved[10]	
165-3 - Irrigated Crops	TEP	—	No	-	No[11]	
165-4 - In Fish	PAIRA/TGAI	A,B,G	No	-	Yes[12]	12 months
165-5 - In Aquatic Non-Target Organism	TEP	G	No	-	Reserved[13]	

TABLE A
GENERIC DATA REQUIREMENTS FOR ETHEPHON

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[1] Composition: TGAI = Technical Grade of the Active Ingredient; PAIRA = Pure Active Ingredient, Radiolabelled; TEP = Typical End Use Product.

[2] The use patterns are coded as follows: A = Terrestrial Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.

[3] Data must be submitted within the indicated timeframe, based on the date of this Guidance Document.

[4] This study is reserved, pending receipt and evaluation of other environmental fate data.

[5] If an anaerobic aquatic study is submitted, then the anaerobic soil study need not be done.

[6] Not required because ethephon has no aquatic or aquatic impact uses.

[7] This data requirement remains unsatisfied because of discrepancies between studies (ethephon was mobile in three soils, including a peat in one study, and immobile in sandy clay loam soils in the other). The registrant must either give an adequate explanation for the discrepancies or submit a new study on the mobility of unaged ethephon. In addition, a study on the mobility of aged ethephon is required.

[8] This data requirement is not being imposed at this time.

[9] These data may be required, depending on the results of the field dissipation studies.

[10] These data may be required, depending on the results of the confined rotational crop study.

[11] Not required because ethephon has no aquatic uses.

[12] Registrant should submit an octanol-water partition coefficient. On the basis of this and other data, the agency will then determine if a study is needed.

[13] This data requirement is reserved, pending results of data required under 165-4.

TABLE A
GENERIC DATA REQUIREMENTS FOR ETHEPHON

Data Requirement	Test Substance[1]	use pattern	Does EPA Have Data2	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Submission
158.390 Reentry Protection						
132-1 - Foliar Dissipation	TEP	A,B	No	-	Yes[3/4]	
132-1 - Soil Dissipation	TEP	A,B	No	-	Yes[3/5]	
133-3 - Dermal Exposure	TEP	A,B	No	-	Conditional[6]	
133-4 - Inhalation Exposure	TEP	A,B	No	-	Conditional[6]	

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[1] TEP = Typical End Use Product.

[2] A = Terrestrial Food Crop Uses; B = Terrestrial Non-Food Uses.

[3] Data must be submitted no later than 18 months after issuance of this document.

[4] For each end use, you must propose an acceptable reentry interval based upon dissipation of residues (decline curve), considering human exposure and toxicity of the residues or on the time when there are no detectable dislogeable or inhalable residues in the field.

[5] Soil dissipation data are required only for uses where workers will be exposed directly to the soil during their work.

[6] Human exposure monitoring data are not required at this time. If dermal exposure data are submitted, then the inhalation exposure data must also be submitted.

TABLE A
GENERIC DATA REQUIREMENTS FOR ETHEPHON

Data Requirement	Test Substance[1]	use pattern	Does EPA Have Data2	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Submission
158.440 Spray Drift						
202-1 - Drift Field Evaluation	TEP	A,B	No	-	Reserved[3]	
202-1 - Drift Size Spectrum	TEP	A,B	No	-	Reserved[3]	

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[1] TEP = Typical End Use Product.

[2] A = Terrestrial Food Crop; B = Terrestrial Non-Food.

[3] This data requirement is being reserved, pending receipt and evaluation of phytotoxicity data required by the Ecological Effects Branch.

GENERIC DATA TABLE FOR ETHEPHON

Data Requirement	Test Substance[1]	use pattern	Does EPA Have Data2	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Submission
158.490 WILDLIFE AND AQUATIC ORGANISMS						
Avian and Mammalian Testing						
71-1 - Avian Oral LD_{50}	TGAI	A,B,G	Yes	00027493	No	
71-2 - Avian Dietary LC_{50}						
Upland game	TGAI	A,B,G	Yes	00085446	No	
	TEP	A,B,G	Yes	00107428	No	
Waterfowl	TGAI	A,B,G	Yes	00005684	No	
71-3 - Wild Mammal	TGAI		No		No[3]	
71-4 - Avian Reproduction	TGAI		No		No[6]	
71-5 - Simulated and Actual Field testing - Mammals and Birds	TEP		No		No[6]	
Aquatic Testing						
72-1 - Freshwater Fish LC_{50}						
Warm water	TGAI	A,B,G	Yes	00027495 00122412	No	
Cold water	TGAI	A,B,G	Yes	00027495	No	
				00122412	No	
72-2 - Acute LC_{50} Freshwater Invertebrates	TGAI	A,B,G	Yes	00054013	No	
	TEP	A,B,G	Yes	00122448	No	

GENERIC DATA TABLE FOR ETHEPHON

Data Requirement	Test Substance[1]	use pattern	Does EPA Have Data[2]	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Submission
Aquatic Testing (Cont.)						
72-3 - Acute LC_{50} Estuarine and Marine Organisms	TGAI	A,B,G	Partially	00054013	Yes[4]	12 months
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life Cycle	TGAI	A,B,G	No		No[6]	
72-5 - Fish Life Cycle	TGAI	A,B,G	No		No[6]	
72-6 - Aquatic Organism Accumulation	TGAI	A,B,G	No		No[6]	
72-7 - Simulated or actual Field Testing - Aquatic Organisms	TEP	A,B,G	No		Reserved[5]	
158.150 PLANT PROTECTION						
121-1 - Target Area Phytotoxicity	TEP	A,B,G	No[6]		No	

GENERIC DATA TABLE FOR ETHEPHON

Data Requirement	Test Substance^1	use pattern	Does EPA Have Data2	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Submission
Non-Target Area Phytotoxicity						
Tier I						
122-1 - Seedling Germination/ Seedling Emergence	TGAI	A,B,G	No		Yes	12 months
122-1 - Vegetative Vigor	TGAI	A,B,G	No		Yes	12 months
122-2 - Aquatic Plant Growth	TGAI	A,B,G	No		Yes	12 months
Tier II						
123-1 - Seed Germination/ Seedling Emergence	TGAI	A,B,G	No		Reserved^7	
123-1 - Vegetative Vigor	TGAI	A,B,G	No		Reserved^7	
123-2 - Aquatic Plant Growth	TGAI	A,B,G	No		Reserved^7	
Tier III						
124-1 - Terrestrial Field	TEP	A,B,G	No		Reserved^8	
124-2 - Aquatic Field	TEP	A,B,G	No		Reserved^8	

GENERIC DATA TABLE FOR ETHEPHON (continued)

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[1] Composition: TGAI = Technical Grade of the Active Ingredient, PAI = Pure Active Ingredient, TEP = Typical End-Use Product.

[2] Use patterns are coded as follows: A = Terrestrial, food crop; B = Terrestrial, non-food; C = Aquatic, food crop; D = Aquatic, non-food; E = Greenhouse, food crop; F = Greenhouse, non-food; G = Forestry; H = Domestic, outdoor; I = Indoor.

[3] Additional data not required because of existing rodent studies.

[4] The requirement for an estuarine/marine shrimp test is fulfilled. Submit either a 96-hour shell deposition study, or a mollusc 48-hour embryo-larvae study. Because the LC_{50} values of freshwater and saltwater crustaceans indicate similar toxicities between fresh and saltwater taxa, and because the toxicity to freshwater fish is low, the requirement is waived for the estuarine/marine fish component of the testing.

[5] Reserved pending the results of outstanding studies.

[6] Not currently a requirement.

[7] Reserved pending results of Tier I studies.

[8] Reserved pending the results of the Tier II studies.

TABLE A
GENERIC DATA REQUIREMENTS FOR ETHEPHON

Data Requirement	Test Substance[1]	use pattern	Does EPA Have Data2	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Submission3
158.590 Nontarget Insect						
NONTARGET INSECT TESTING - POLLINATORS:						
141-1 - Honey bee acute contact LD_{50}	TGAI	A,B	Yes	00018842	No	
141-2 - Honey bee - Toxicity of residues on foliage	TEP	A,B	No		No[3]	
141-4 - Honey bee subacute feeding study	[Reserved][4]					
141-5 - Field testing for pollinators	TEP	A,B	No		No[3]	
NONTARGET INSECT TESTING - AQUATIC INSECTS						
142-1 - Acute toxicity to aquatic insects	[Reserved][5]					
142-2 - Aquatic insect life-cycle study	[Reserved][5]					
142-3 - Simulated or actual field testing for aquatic insects	[Reserved][5]					
143-1 thru 143-3 - NONTARGET INSECT TESTING-PREDATORS AND PARASITES	[Reserved][5]					

TABLE A
GENERIC DATA REQUIREMENTS FOR ETHEPHON

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[1] Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.

[2] The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.

[3] As data from the acute contact test indicate low toxicity, no further testing is required.

[4] Reserved pending development of test methodology.

[5] Reserved pending Agency decision as to whether the data requirement should be established.

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING ETHEPHON

Data Requirement	Test Substance[1]	Does EPA Have Data[2]	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Submission[3]
158 Subpart C Product Chemistry					
Product Identity and Composition					
61-1 - Product Identity and Disclosure of Ingredients	MP	No	N/A	Yes[4]	6 months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	No	N/A	Yes[5]	6 months
61-3 - Discussion of Formation of Impurities	MP	No	N/A	Yes[6]	6 months
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis of Product Samples	MP	No	N/A	Yes[7]	12 months
62-2 - Certification of Ingredient Limits	MP	No	N/A	Yes[8]	12 months
62-3 - Analytical Methods to Verify Certified Limits	MP	No	N/A	Yes[9]	12 months
Physical and Chemical Characteristics					
63-2 - Color	MP	No	N/A	Yes[10]	6 months
63-3 - Physical State	MP	No	N/A	Yes[10]	6 months
63-4 - Odor	MP	No	N/A	Yes[10]	6 months
63-7 - Density, Bulk Density or Specific Gravity	MP	No	N/A	Yes[10]	6 months
63-12 - pH	MP	No	N/A	Yes[10,11]	6 month
63-14 - Oxidizing or Reducing Action	MP	No	N/A	Yes[10,12]	6 month
63-15 - Flamability	MP	No	N/A	Yes[10,13]	6 month
63-16 - Explodability	MP	No	N/A	Yes[10,14]	6 month
63-17 - Storage Stability	MP	No	N/A	Yes[10]	15 months
63-18 - Viscosity	MP	No	N/A	Yes[10,15]	6 month

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING ETHEPHON

Data Requirement	Test Substance[1]	Does EPA Have Data[2]	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Submission[3]
158 Subpart C Product Chemistry (Cont.)					
63-19 - Miscibility	MP	No	N/A	Yes[10,16]	6 months
63-20 - Corrosion Characteristics	MP	No	N/A	Yes[10]	15 months
Other Requirements:					
64-1 - Submittal of Samples	N/A	N/A	N/A	No	

[1] Composition: MP = Manufacturing-Use Product.

[2] Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

[3] Data must be submitted within the indicated timeframe, based on the date of this Guidance Document.

[4] The chemical name, nominal concentration, Chemical Abstracts (CAS) Registry Number, and purpose of the active ingredient and each intentionally added inert must be provided. For the active ingredients, the following must also be provided: the product, common,and trade names; the molecular, structural, and empirical formulas; the molecular weight or weight range; and any experimental or internally assigned company code numbers.

[5] Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material used in the manufacture of each product must be provided, along with information regarding the properties of those materials.

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING ETHEPHON

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[6] A detailed discussion of all impurities that are or may be present at $\geq$ 0.1 percent, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted.

[7] Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which certified limits are required. Complete validation data (accuracy and precision) must be submitted for each analytical method used.

[8] Upper and lower limits for the active ingredient and each intentionally added inert, and upper limits for each impurity present at $\geq$ 0.1 percent (w/w) and each "toxicologically significant" impurity present at < 0.1 percent (w/w) must be provided and certified. Also, an explanation of how each certified limit was established must be provided (e.g., sample analysis using validated analytical procedures, quantitative estimate based on amounts of ingredients used, etc.). Limits for impurities not associated with the active ingredient need be provided only if they are considered to be of toxicological significance, regardless of the concentration at which they are present (2-chloroethanol). Certifications must be submitted on EPA Form 8570 Rev. 2-85.

[9] Analytical methods must be provided to determine the active ingredient, and each toxicologically significant impurity and intentionally added inert for which certified limits are required. Each method must be accompanied by validation studies indicating its accuracy and precision. These methods must be suitable for enforcement of certified limits.

[10] Physicochemical characteristics (color, physical state, odor, melting point, boiling point, specific gravity, solubility, vapor pressure, dissociation constant, partition coefficient, pH, and stability) as required in 40 CFR 158.120 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, must be submitted.

[11] Data required if the test substance is dispersible in water.

[12] Data required if the product contains oxidizing or reducing agents.

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING ETHEPHON

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[13] Data required if the product contains combustible liquids.

[14] Data required if the product is potentially explosive.

[15] Data required if the product is a liquid.

[16] Data required if the product is a liquid and is to be diluted with petroleum solvents.

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING ETHEPHON

Data Requirement	Test Substance[1]	Does EPA Have Data[2]	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Submission[3]
158.340 Toxicology					
ACUTE TESTING:					
81-1 - Acute Oral - Rat	MP	Yes	00029509	No	
81-2 - Acute Dermal	MP	Yes	00029510	No	
81-3 - Acute Inhalation - Rat	MP	No	-	Yes	
81-4 - Eye Irritation - Rabbit	MP	No	-	No[3]	
81-5 - Dermal Irritation - Rabbit	MP	Yes	00029513	No	
81-6 - Dermal Sensitization - Guinea Pig	MP	No	-	Yes	

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[1] Composition: MP = Manufacturing-use product.

[2] Unless otherwise specified data must be submitted no later than six months after publication of this standard.

[3] Primary Eye Irritation Studies are not required for substances which are corrosive in Primary Dermal Irritation Studies. Since ethephon is corrosive, an Primary Eye Irritation Study is not required.

SUMMARY-1

LABEL CONTENTS

40 CFR 156.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 156.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 156.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 156.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 156.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 156.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 156.10(h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 156.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 156.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 156.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 156.10(h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 156.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 156.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR Part 152, Subpart I. You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 156.10(h)(1)(iv)

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

SUMMARY-5

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 156.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-6

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

§162.10 Labeling requirements.

(a) General--(1) Contents of the label. Every pesticide product shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) Prominence and legibility. (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) Language to be used. All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) Placement of Label--(i) General. The label shall appear on or be securely attached to the immediate container of the

pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) Tank cars and other bulk containers--(A) Transportation. While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) Storage. When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) False or misleading statements. Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling*. (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark*. (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for ***," "Distributed by ***," or "Sold by ***" to show that the name is not that of the producer.

(d) *Net weight or measure of contents*. (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68°F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) Product registration number. The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) Producing establishments registration number. The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) Ingredient statement--(1) General. The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) Position of ingredient statement. (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) Names to be used in ingredient statement. The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) Statements of percentages. The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) Accuracy of stated percentages. The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) Deterioration. Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) Inert ingredients. The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) Warnings and precautionary statements. Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) Required front panel statements. With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC_{50}	Up to and including .2 mg/liter	From .2 thru 2 mg/liter	From 2 thru 20 mg/liter	Greater than 20 mg/liter
Dermal LD_{50}	Up to and including 200 mg/kg	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000
Eye effects	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin effects	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

(i) Human hazard signal word.--(A) Toxicity Category I. All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) Toxicity Category II. All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) Toxicity Category III. All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) Toxicity Category IV. All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) Use of signal words. Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) Child hazard warning. Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) Statement of practical treatment--(A) Toxicity Category I. A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) Other toxicity categories. The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) Placement and prominence. All the required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) Other required warnings and precautionary statements. The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) Hazard to humans and domestic animals. (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I . . .	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust] or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II . . .	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.].
III . . .	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV . . .	[No precautionary statements required.].	[No precautionary statements required.].

(ii) Environmental hazards. Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) Physical or chemical hazards. Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20°F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
Flash point above 20°F and not over 80°F or if the flame extension is more than 18 in. long at a distance of 6 in. from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20°F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20°F and not over 80°F	Flammable. Keep away from heat and open flame.
Above 80°F and not over 150°F	Do not use or store near heat or open flame.

(i) *Directions for Use*--(1) *General requirements*--(i) *Adequacy and clarity of directions*. Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use*. Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular." and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*--(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) Contents of Directions for Use. The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment requried.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) Statement of Use Classification. By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) General Use Classification. Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) Restricted Use Classification. Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) Front panel statement of restricted use classification. (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 38571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

PHYSICAL/CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. All Other Pressurized Containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STOR-1

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PEST/DIS-1

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

CONT/DIS-1

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

[1] Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

GUIDE TO USE OF THIS BIBLIOGRAPHY

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

  (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

  (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

  (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

  (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Ethephon Standard

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Citations Considered to be Part of the Data Base Supporting Registrations Under the Ethephon Standard

MRID	CITATION
00030190	Hegidio, J.; Dyson, D.; Thomas, N.B.; et al. (1979) Residues. Includes method dated Oct 1979. (Unpublished study received Dec 19, 1979 under 264-267; prepared in cooperation with Salyer Land Co. and others, submitted by Union Carbide Agricultural Products Co., Ambler, Pa.; CDL:099158-C)
00032573	Harrison, S.L.; Nygren, R.E.; Gross, S.M.; et al. (1980) Residues: Ethrel/Sugarcane: Project No. 10223. (Unpublished study received May 15, 1980 under 264-EX-59; prepared in cooperation with Hawaiian Sugar Planters' Association, submitted by Union Carbide Agricultural Products Co., Ambler, Pa.; CDL:099427-A)
00036500	Obenauf, G.L. (1973) Residues: [Ethephon]. (Unpublished study received Mar 19, 1974 under 4F1490; prepared in cooperation with Greenwood Laboratories, Inc., submitted by Union Carbide Agricultural Products Co., Ambler, Pa.; CDL:093944-B)
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MRID	CITATION
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00042977	Union Carbide Agricultural Products Company (19??) Analysis of Pineapple Tissue for Residues of 2-Chloroethylphosphonic acid. Undated method. (Unpublished study received Dec 23, 1969 under 264-257; CDL:100700-D)
00047911	Westwood, M.; Anderson, J.L.; Edgerton, L.; et al. (1971) Validation of Analytical Method. (Unpublished study including letter dated Aug 4, 1971 from S.L. Harrison to Richard J. Otten, received Jun 16, 1971 under 1G1172; prepared in cooperation with Oregon State Univ. and others, submitted by Union Carbide Agricultural Products Co., Ambler, Pa.; CDL:093494-A)
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MRID	CITATION
00054013	Bentley, R.E. (1974) Acute Toxicity of Technical Ethrel to Grass Shrimp (Palaemonetes vulgaris), Mud Crab (Neopanope texana) Water Flea (Daphnia magna), Midge Larvae (Chironomus tentans), and Scud (Gammarus fasciatus). (Unpublished study received Dec 5, 1974 under 264-292; prepared by Bionomics, EG&G, Inc., submitted by Union Carbide Agricultural Products Co., Inc., Ambler, Pa.; CDL:230425-R)
00054018	Yamaguchi, M.; Chu, C.W.; Yang, S.F. (1971) Metabolism of Ethephon in Tomatoes. (Unpublished study received Jun 7, 1972 under 2G1195; prepared by Univ. of California--Davis, Dept. of Vegetable Crops, submitted by Union Carbide Agricultural Products Co., Inc., Ambler, Pa.; CDL:091010-B)
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00085446	Fink, R.; Beavers, J.B.; Brown, R. (1977) Final Report: Eight-day Dietary LC:50--Bobwhite Quail: Project No. 113-139. (Unpublished study received Mar 2, 1979 under 264-267; prepared by Wildlife International, Ltd. and Washington College, submitted by Union Carbide Agricultural Products Co., Inc., Ambler, Pa.; CDL:097830-F)
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00103287	Harrison, S.; Madgwick, G. (1982) Residues of Ethephon in Wheat, Barley and Oats Resulting from Application of Ethrel as an Anti-lodging Agent: File No. 30263. (Unpublished study received Jun 17, 1982 under 264-376; submitted by Union Carbide Agricultural Products Co., Inc., Research Triangle Park, NC; CDL:070929-D)
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00108992	Fritz, D.; Barden, J.; Edgerton, L. (1971) Residues: [Ethepon in Apples]. (Unpublished study received Jul 15, 1972 under 2G1217; prepared in cooperation with Virginia Polytechnic Institute and Cornell Univ., submitted by Amchem Products, Inc., Ambler, PA; CDL:091045-A)
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MRID	CITATION
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00136287	Amchem Products, Inc. (1972) [Residues: Ethephon]. (Compilation; unpublished study received Oct 3, 1972 under 3F1321; CDL: 092129-B)
00141506	Heintzelman, R. (1984) Ethephon Goat Metabolism: V5007. Unpublished study prepared by Union Carbide Agricultural Products Co., Inc. 11 p.
00142265	Huhtanen, K. (1984) Cerone: Detailed Methods of Analysis for Residue of (2-Chloroethyl) Phosphonic Acid (Ethephon) in Milk and Cow Liver, Muscle, Kidney and Fat Tissues: Project Number: 866R10. Unpublished study prepared by Union Carbide Agricultural Products Co., Inc. 20 p.
00144559	Fletcher, D. (1983) 42-Day Neurotoxicity Study with Ethephon:Base 250 in Mature White Leghorn Chickens: BLAL No. 83 DN 102. Unpublished study prepared by Bio-Life Assoc., Ltd. 52 p.
00145613	Union Carbide Agricultural Products Co. (1984?) Residue Summary: Ethephon Residue Data:. Unpublished compilation. 59 p.
00165339	Huhtanen, K.; Storm, J.; Heintzelman, R. (1984) Ethrel: Metabolism of Carbon 14:-ethephon in Lactating Goats: Project No. 866R10: File No. 32452. Unpublished study prepared by Union Carbide Agricultural Products Co., Inc. 39 p.
40632101	Interregional Research Project No. 4 (1979) The Amount of Ethephon Residues Remaining in or on Guava Fruit. Prepard by Agricultural Biochemistry Department, University of Hawaii. 40 p.

OMB Approval No. 2000-046

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET

EPA REGISTRATION NO

PRODUCT NAME

APPLICANT'S NAME

DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products).

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

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OMB Approval No. 2070-0057
Expiration Date 11/30/89

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number: ______________

Registrant's Name and Address: ______________________________________

____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated __________ concerning a requirement for submission of generic data on the active ingredient __________ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate Confidental Statement of Formula(CSF) for the above-identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product, or

The CSF dated ________ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form No. 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are ______________ and their registration number(s) is/are ____________.

(4) My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product to one that is not registered and purchased.

(5) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA Section 3(c)(2)(B).

(6) I further understand that if my firm is granted a generic data exemption for the product, my firm relies on the efforts of other persons to provide the Agency with the required generic data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Notice's data requirements, the Agency will consider that both they and my firm are not in compliance and will normally initiate proceedings to suspend the registrations of my firm's product(s) and their product(s), unless my firm commits to submit and submits the required data in the specified time frame. I understand that, in such cases, the Agency generally will not grant a time extension for submitting the data.

Registrant's authorized representative: ______________________________
(Signature)

Dated: ______________ ______________________________
(Typed)

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No.______________________ Date ______________________

Registration Standard for ______________________

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) MRID Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
Part 158 Subpart C PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) MRID Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.340 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

OMB Approval No. 2000-0468

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:	GUIDANCE DOCUMENT DATE ACTIVE INGREDIENT
NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of these firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6 (10-82)

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